Cognizant

Digital Clinical

Future of Clinical Trials and Data Management

Inder Sachdeva

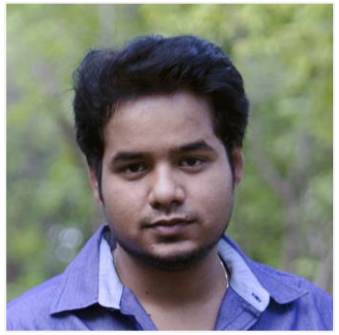
Phuse SDE 27th July 2019

DISCLAIMER

Content, Views and Opinions Expressed in this presentation are solely of the **Author/s** & **Presenters** and do not necessarily represent official policy or position or views of **Cognizant.**

APPRECIATIONS

Loads of Thanks to colleagues of mine who helped me put this presentation together!



KRIPENDRA SINGH
Cognizant

NEELAM MAURYA
Cognizant

ANIRBAN GHOSH
Cognizant

JESIKA VORA
Cognizant

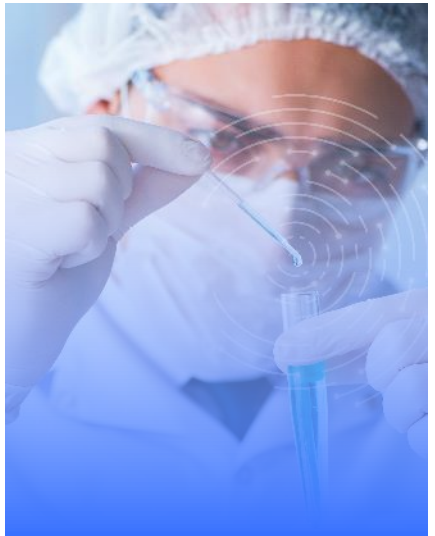
ABHISHEK MONDAL
Cognizant

RUPALI PATANKAR
Cognizant

Cognizant

FLOW

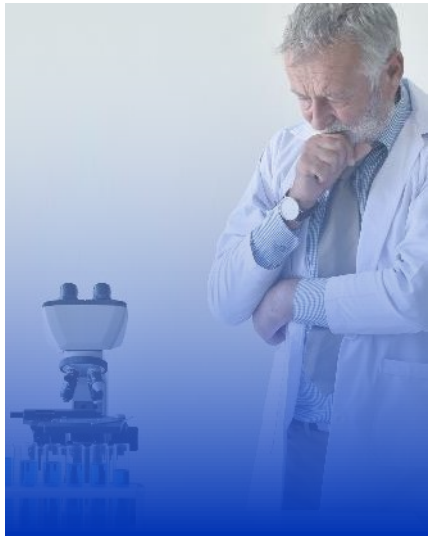
Focus Digital



Trials and Digital Landscape

Rising Complexity in Clinical Trial Landscape

Innovative Technologies in Works



Questions

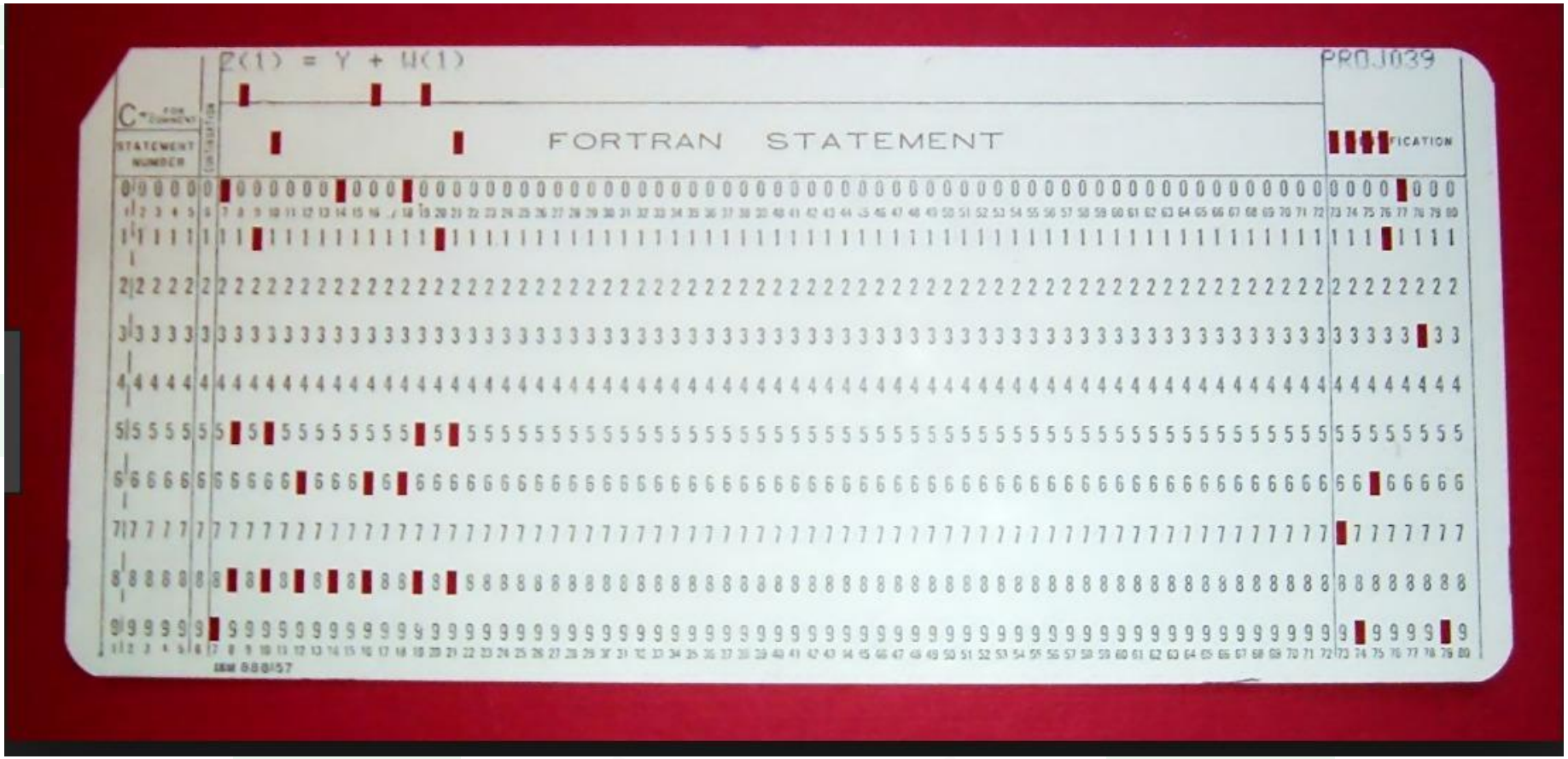
Cognizant

AGENDA TOPIC

INDUSTRY 4.0

Avoiding digitization and modernization ‘not an option’

Cognizant



Exit

01

Focus Digital

How FDA Has Been Changing

Patient Centricity and Safety

(< Pre 2010)

2003

The **Pediatric Research Equity Act**

2004

FDA's report on **Innovation or Stagnation**

2005

The **Drug Safety Board** is formed,

2006

New FDA guidance for **out-of-specification test results**

2007

FDA **Access to Results of Quality Assurance Program Audits and Inspections**

2009

FDA **Releases Revision To Q8 Pharmaceutical Development Guidance**

2009

Patient-Reported Outcome Measures: Use in Medical Product Development to Support Labeling Claims

References: https://www.fda.gov/news-events/fda-newsroom/press-announcements?page=1

How FDA Has Been Changing

Newer Approaches

(< 2010-2015)

2011

FDA Guidance for **Industry Update – Process Validation**

2012

Guidance for Industry on Enrichment Strategies for Clinical Trials to Support **Approval Of Human Drugs And Biological Products**

2013

FDA Guidance and EMA reflection paper on **Risk-based Monitoring** & FDA Guidance on **Electronic Source Data in Clinical Investigations**

2014

FDA Releases New Guidance On Establishing Safety, **Compatibility Of Passive Implants** In MR Environments

References: https://www.fda.gov/news-events/fda-newsroom/press-announcements?page=1

How FDA Has Been Changing

Digital & Technology

(< Since 2015)

References: https://www.fda.gov/news-events/fda-newsroom/press-announcements?page=1

Cognizant

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
FDA.GOV

U.S. FOOD & DRUG ADMINISTRATION

FDA FACT SHEET

THE FDA'S ROLE IN MEDICAL DEVICE CYBERSECURITY

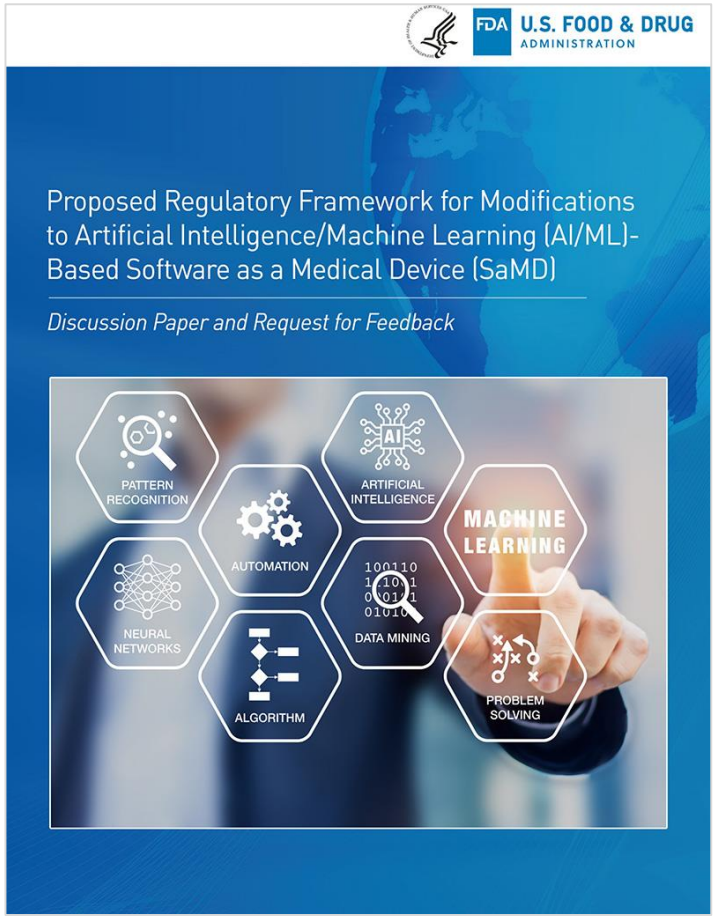
Dispelling Myths and Understanding Facts

As medical devices become more digitally interconnected and interoperable, they can improve the care patients receive and create efficiencies in the health care system. Medical devices, like computer systems, can be vulnerable to security breaches, potentially impacting the safety and effectiveness of the device. By carefully considering possible cybersecurity risks while designing medical devices, and having a plan to manage emerging cybersecurity risks, manufacturers can reduce cybersecurity risks posed to devices and patients.

The International Medical Device Regulators Forum (IMDRF) defines 'Software as a Medical Device (SaMD)' as software intended to be used for one or more medical purposes that perform these purposes without being part of a hardware medical device.1 FDA, under the Federal Food, Drug, and Cosmetic Act (FD&C Act) considers medical purpose as those purposes that are intended to treat, diagnose, cure, mitigate, or prevent disease or other conditions.

References: https://www.fda.gov/news-events/fda-newsroom/press-announcements?page=1

Proposed Regulatory Framework for Modifications to Artificial Intelligence/Machine Learning(AI/ML) – Based Software as a Medical Device (SaMD)

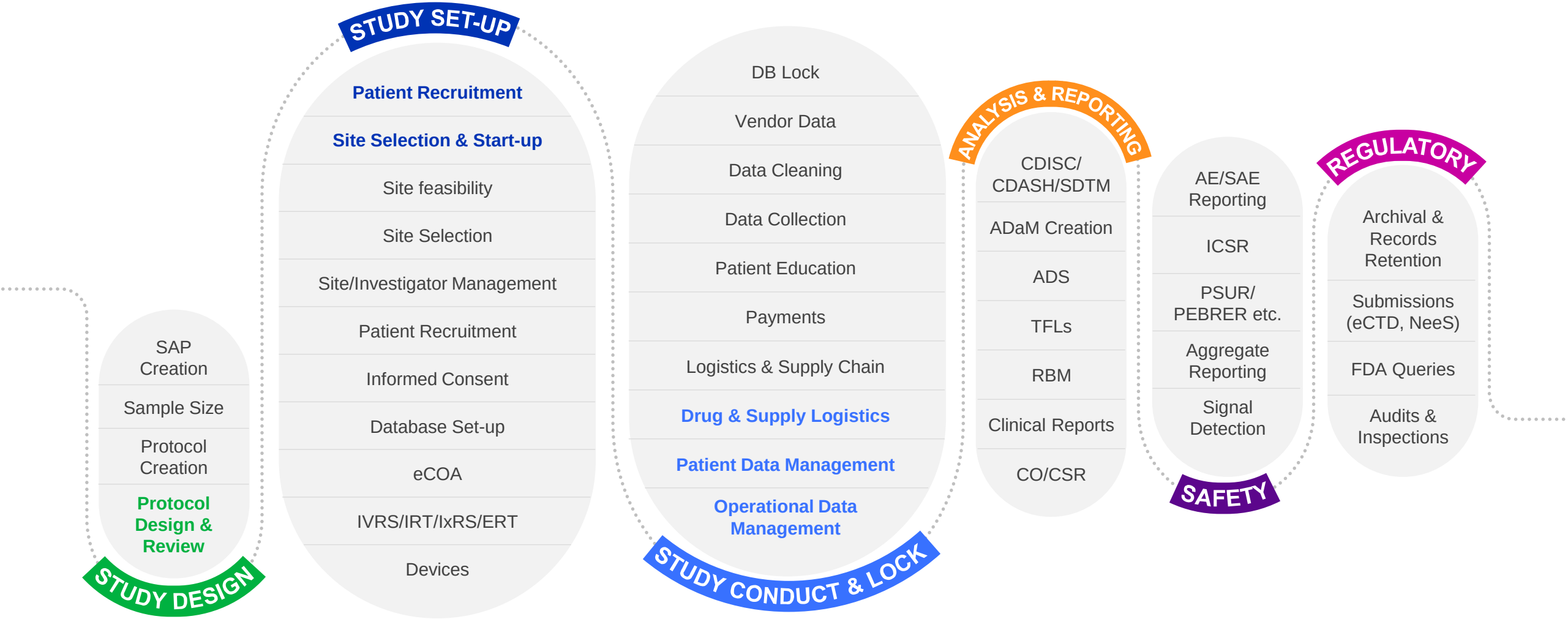


References: https://www.fda.gov/news-events/fda-newsroom/press-announcements?page=1

02

Trials and Digital Landscape

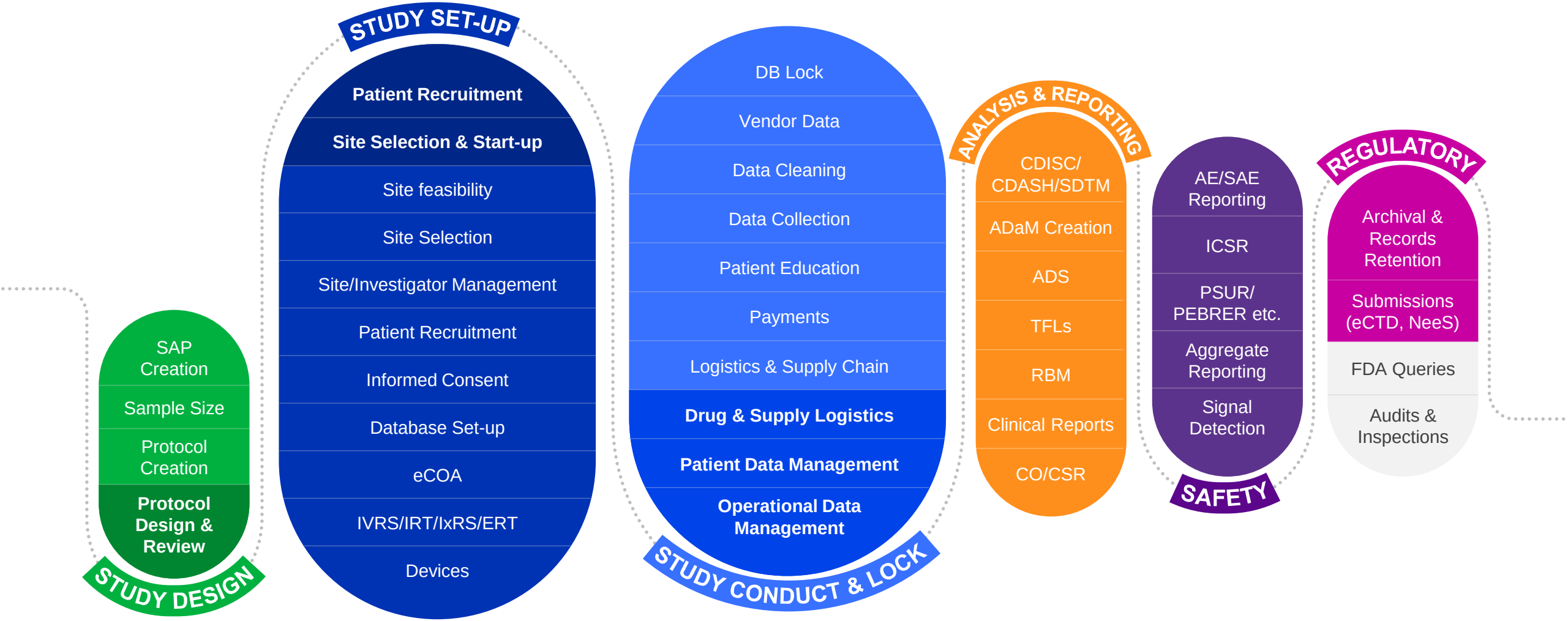
End to End Clinical Trial Chain



Cognizant

End to End Clinical Trial Chain

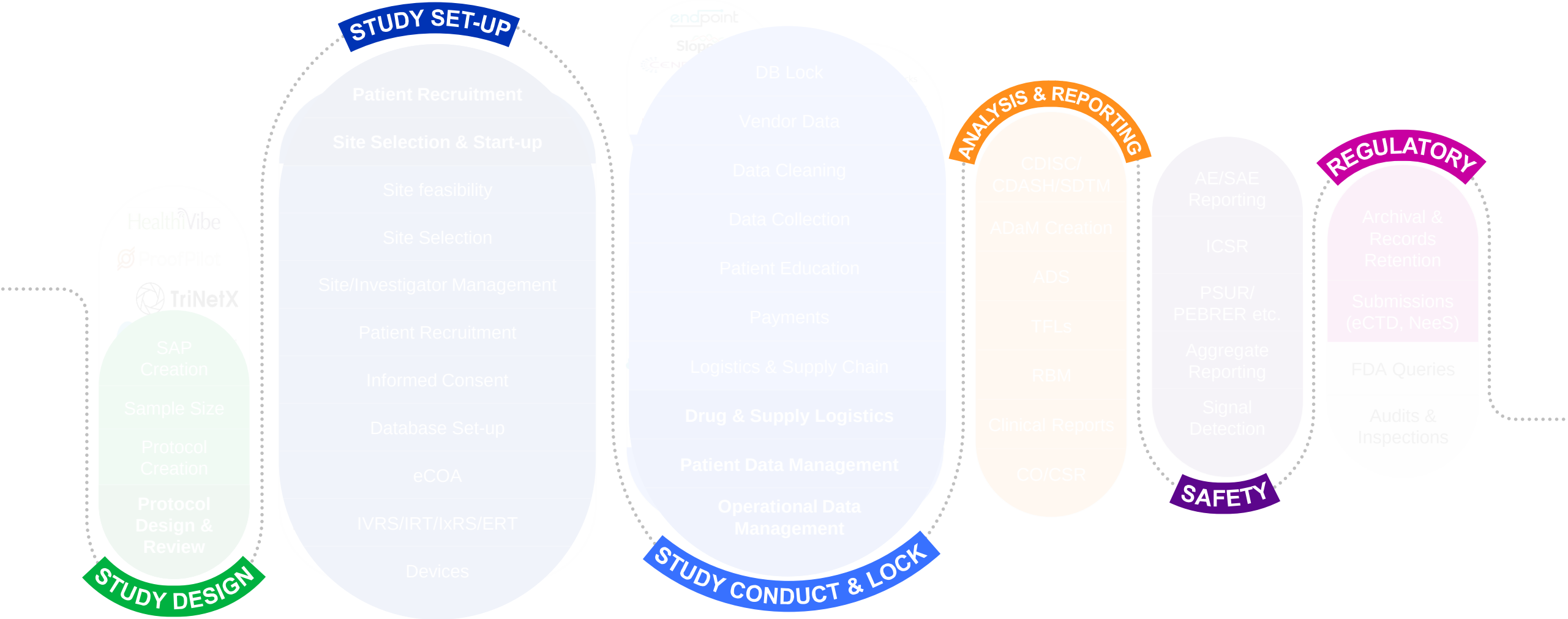
What's Digitally Available



Cognizant

End to End Clinical Trial Chain

What's Digitally Available



https://blog.andreacoravos.com/software-enabled-clinical-trials-8da53f4cd271?gi=10c9c1b855ec

Cognizant

03

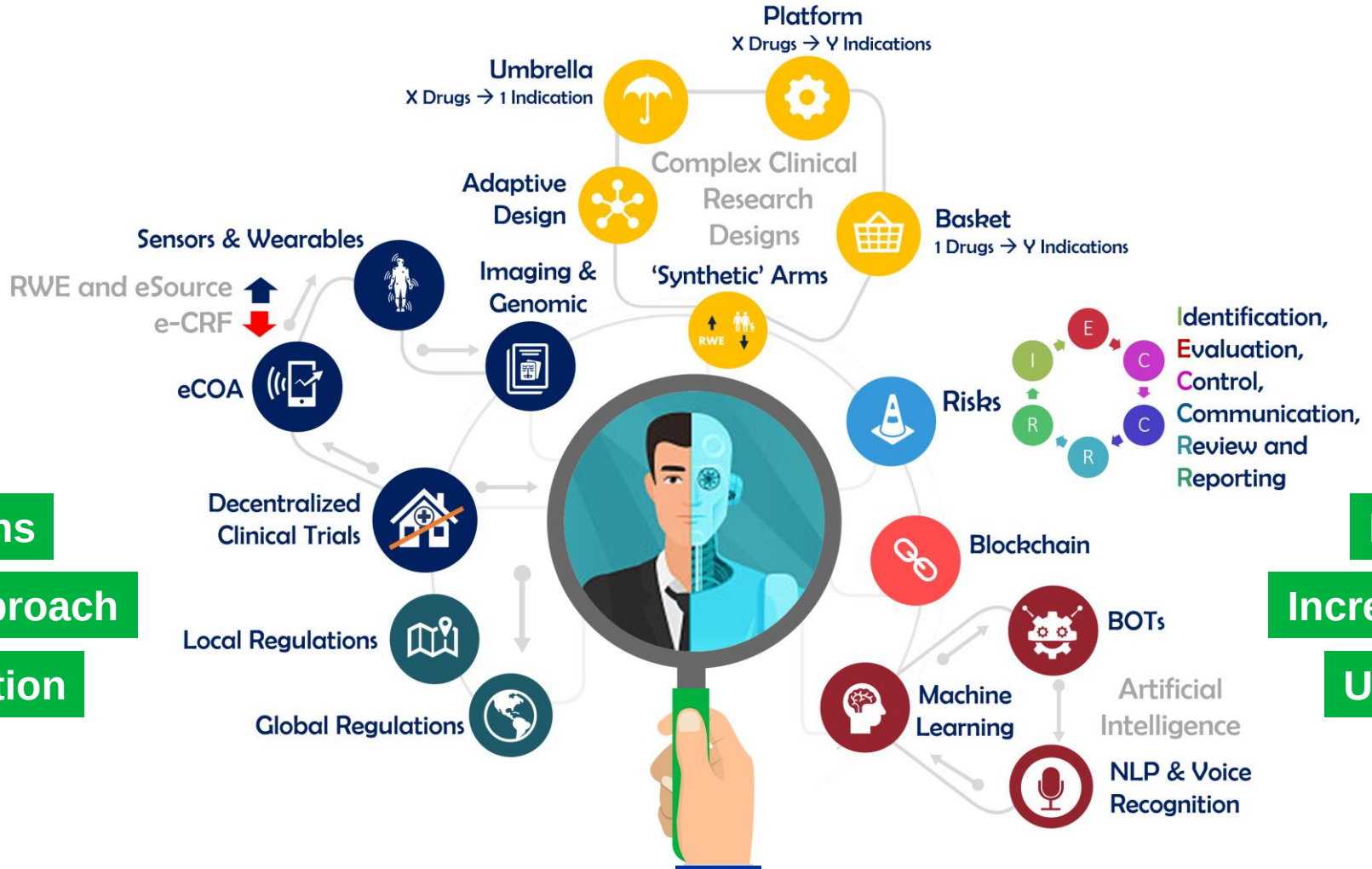
Need to reduce Costs, Timelines & Improve Efficiency

Rise in Operational Complexity

Need for Newer Technologies which can adapt with changing design (Future Proof Platforms)

Patient Centricity Leading to Decentralization

New World of Clinical Research – Operational Complexity



Trial Designs

Risk Based Approach

Decentralization

Newer Devices

Increasing Regulations

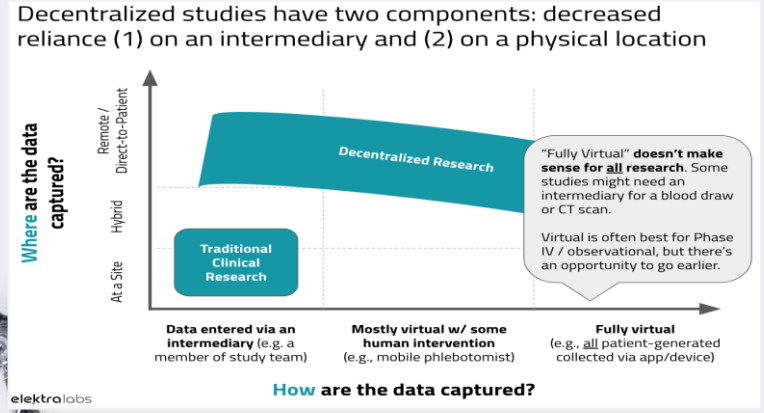
Use of AI/ML/NLP

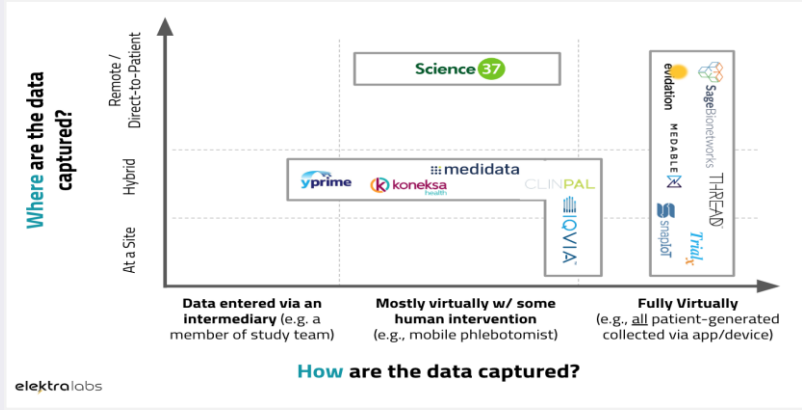
Clinical Data Scientist & Clinical Data Manager

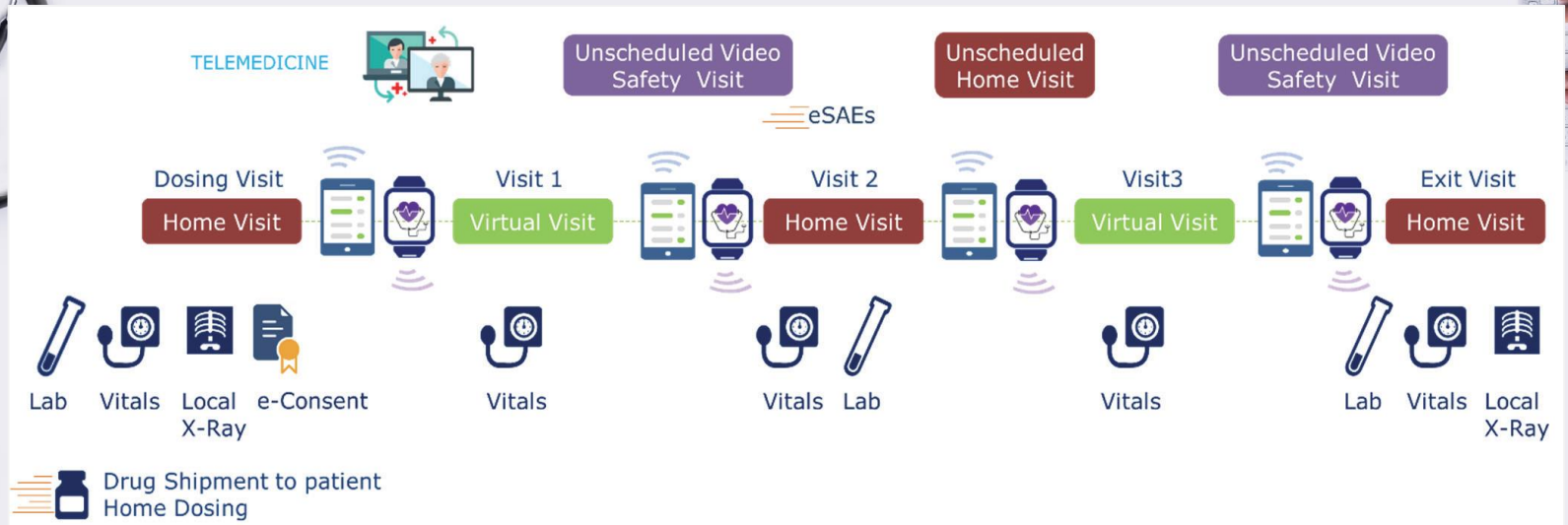
https://www.scdm.org/publications/white-papers/

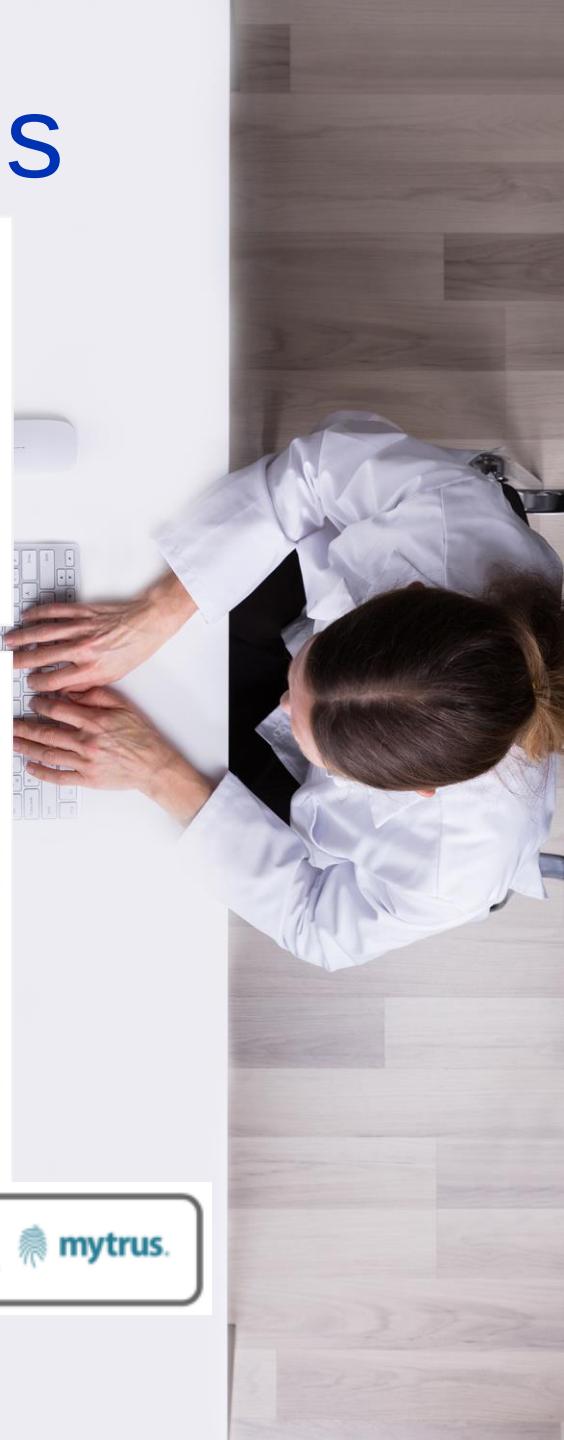
Cognizant

Virtual Or Decentralized Trials





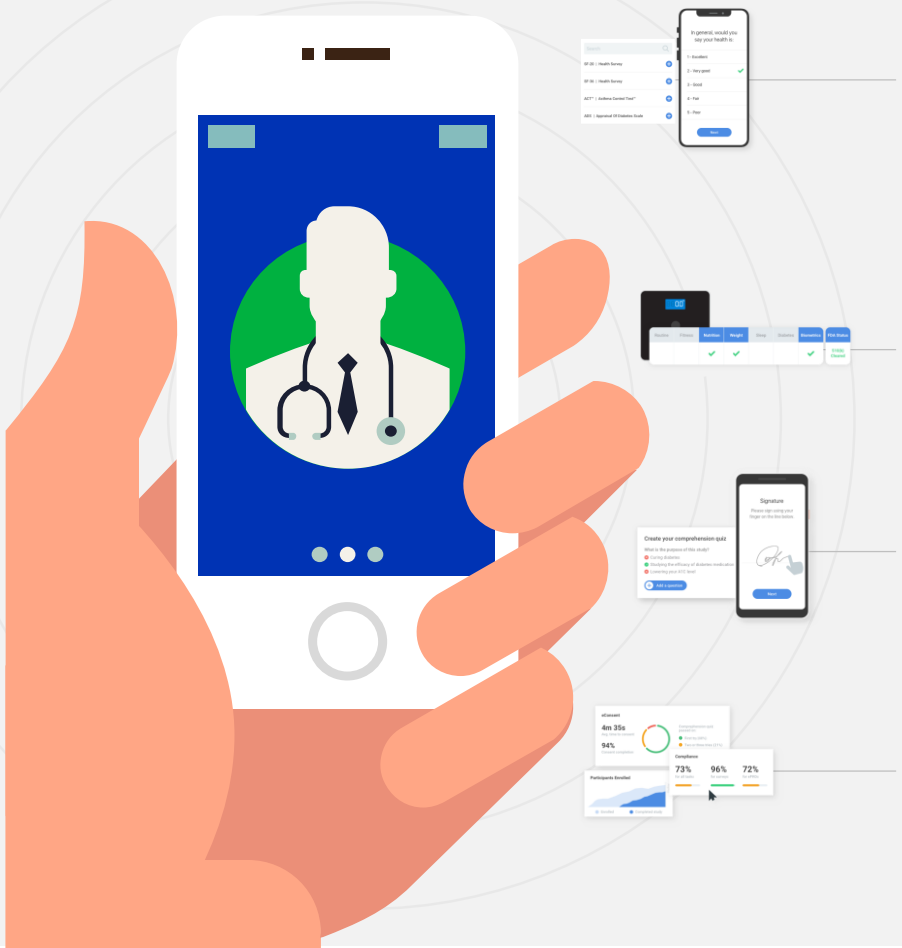




Virtual Trials Science 37 MEDABLE Sage evidation aces HEALTH CLINPAL THREAD aparito EmpiraMed monARC BIONETWORKS mytrus.

https://blog.andreacoravos.com/decentralized-clinical-trials-e9dbde90ea95

eSource Trials: **Replace some clinic visits with Virtual Visits**



ePRO Library: Electronic Patient Reported Outcomes

ePRO library allows you to simply add validated and digitally licensed ePROs to your studies within each iOS and Android patient-facing app.

Integrated Sensors:

Pre-built integrations with wearables, medical devices and health apps for use in research studies to simply navigate to desired device.

Mobile eConsent:

Standardized and cost effective

Real-time Data Access:

Benefit from continual access to study data. Extract key insights and observe study performance in real time and fully integrate into existing data systems to meet data transfer requirements

Standards: eSource Data Interchange (eSDI) Document

The purpose of the eSDI document is "to investigate the use of electronic technology in the context of existing regulations for the collection of eSource data (including that from eDiaries, EHR, EDC) in clinical trials for regulatory submission by leveraging the power of the CDISC standards, in particular the Operational Data Model (ODM)".

The eSDI Document includes:

- An extensive review and analysis of the relevant existing regulations
- Twelve requirements for conducting regulated clinical research using eSource data collection in the context of existing regulations
- Five potential scenarios, three of which include the use of electronic health record systems (EHR), and associated benefits of standards
- An Appendix on Responsibilities of each of the various functional groups conducting clinical research
- A Template for evaluating an eSource data collection process against the requirements
- A Good Practices Checklist for Investigators

http://www.appliedclinicaltrialsonline.com/esource-records-clinical-research
https://www.bioclinica.com/blog/future-esource

Cognizant

04

Innovative Technologies in Works..

Patient-Level Integration: Digital Biomarker Collection

Digital biomarkers are consumer-generated digital tools that collect behavioral and physiological data. These tools can be used to diagnose and/or treat patients remotely i.e. **(a) the sensors and tools that collect the data and (b) the systems that integrate that data.**

Google's
Verily has recently launched Project Baseline, a collaboration of Duke University and Stanford University that will enroll 10,000 healthy people for the study. The study will likely use survey data along with sensor data from the Study Watch, a sensor-packed smartwatch Verily launched in April.

Qualcomm Life's 2Net
is a "non-exclusive, open, and interoperable" platform that has partnered with over "400 collaborators including medical device manufacturers, health service providers, app developers, and more."

Validic
is a technology platform that provides "access to a world of mobile health and in-home devices, fitness equipment, clinical sensors, activity wearables, smart bands and wellness applications."

Vivify Health
is a remote care service provider that has created customized "kits" that include 4g tablets with wireless vitals monitors.

HumanAPI
is similarly building a "real-time health data network, powering more than 10,000 applications in 40 countries."

Actigraph
provides medical-grade wearable activity and sleep monitoring solutions for the global research community.

Apple
has been heavily investing in **ReasearchKit,** developing customized apps and products for a range of conditions.

AliveCor
has developed a FDA-cleared single-lead EKG.

Evidation
Health is building a solution to help companies quantify their digital outcomes, focusing on research with connected devices.

Digital Biomarker Collection[4]

Human API · VALIDIC · evidation · koneksa health · Biospective · ActiGraph · AliveCor · 2net · PHILIPS · ResearchKit · vivifyhealth

https://blog.andreacoravos.com/decentralized-clinical-trials-e9dbde90ea95

Cognizant

Can all this be achieved without Digitization and Modernization?

AGENDA TOPIC

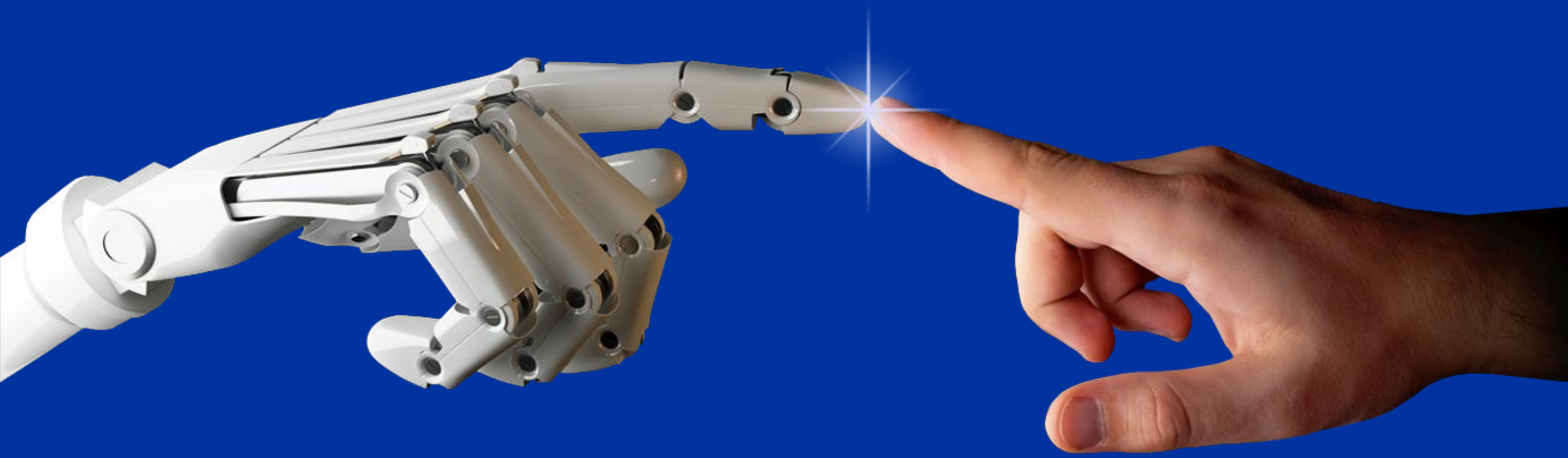
INDU Y 4.0

Avoidin on and modernization ‘not an option’

Cognizant

Questions ???

To be more DIGITAL, you need to be more HUMAN



Cognizant

Cognizant

Thank you!